

# Preface

The purpose of this Report is to provide guidance to researchers in preparing protocols that include ionizing radiation exposure to human subjects and to provide guidance to reviewing bodies, such as Institutional Review Boards, in the process of reviewing such protocols. This includes guidance for assessing proper utilization of radiation, estimation of risk, optimization of radiation dose, and formulation of informed consent statements with consistent, comprehensible and accurate language.

These issues have been dealt with in part by previous National Council on Radiation Protection and Measurements (NCRP) reports, which were generally focused on specific issues, modalities, and/or patient populations. Proper utilization, optimization, and/or informed consent were specifically targeted in:

- Report No. 70, *Nuclear Medicine—Factors Influencing the Choice and Use of Radionuclides in Diagnosis and Therapy* (1982);
- Report No. 99, *Quality Assurance for Diagnostic Imaging* (1988);
- Report No. 102, *Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energies Up to 50 MeV (Equipment Design, Performance and Use)* (1989);
- Report No. 128, *Radionuclide Exposure of the Embryo/Fetus* (1998);
- Report No. 149, *A Guide to Mammography and Other Breast Imaging Procedures* (2004);
- Report No. 155, *Management of Radionuclide Therapy Patients* (2006);
- Report No. 168, *Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures* (2010);
- Report No. 170, *Second Primary Cancers and Cardiovascular Disease After Radiation Therapy* (2011);
- Report No. 172, *Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States* (2012); and
- Report No. 174, *Preconception and Prenatal Radiation Exposure: Health Effects and Protective Guidance* (2013).

Many of these concepts apply not only to the procedures encountered in normal standard of care for medical practice but also to human trials involving exposure to ionizing radiation.

Specific NCRP documents have also addressed the issues of radiation biological effectiveness, radiation dose, and risk estimation. Examples include:

- Report No. 96, *Comparative Carcinogenicity of Ionizing Radiation and Chemicals* (1989);
- Report No. 104, *The Relative Biological Effectiveness of Radiations of Different Quality* (1990);
- Report No. 115, *Risk Estimates for Radiation Protection* (1993);
- Report No. 116, *Limitation of Exposure to Ionizing Radiation* (1993);
- Report No. 126, *Uncertainties in Fatal Cancer Risk Estimates Used in Radiation Protection* (1997);
- Report No. 136, *Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation* (2001);
- Report No. 158, *Uncertainties in the Measurement and Dosimetry of External Radiation* (2007);
- Report No. 160, *Ionizing Radiation Exposure of the Population of the United States* (2009);
- Report No. 164, *Uncertainties in Internal Radiation Dose Assessment* (2009);
- Report No. 167, *Potential Impact of Individual Genetic Susceptibility and Previous Radiation Exposure on Radiation Risk for Astronauts* (2010);
- Report No. 171, *Uncertainties in the Estimation of Radiation Risks and Probability of Disease Causation* (2012);
- Report No. 180, *Management of Exposure to Ionizing Radiation: Radiation Protection Guidance for the United States (2018)* (2018);
- Report No. 181, *Evaluation of the Relative Effectiveness of Low-Energy Photons and Electrons in Inducing Cancer in Humans* (2018); and
- Commentary No. 27, *Implications of Recent Epidemiologic Studies for the Linear-Nonthreshold Model and Radiation Protection* (2018).

Although the risks of low-level radiation exposure remain controversial, high levels of radiation exposure are well known to cause tissue effects (such as skin burns and epilation) and stochastic effects (such as cancer or second primary cancers).

In this and other reports, the NCRP has considered various alternatives to ionizing radiation for medical procedures. Examples of these applications and their potential health effects include:

- Report No. 74, *Biological Effects of Ultrasound: Mechanisms and Clinical Implications* (1983);
- Report No. 86, *Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields* (1986);

- Report No. 113, *Exposure Criteria for Medical Diagnostic Ultrasound: I. Criteria Based on Thermal Mechanisms* (1992);
- Report No. 119, *A Practical Guide to the Determination of Human Exposure to Radiofrequency Fields* (1993); and
- Report No. 140, *Exposure Criteria for Medical Diagnostic Ultrasound: II. Criteria Based on All Known Mechanisms* (2002).

Other nonionizing radiation techniques, such as thermal imaging (passive mapping of infrared energy from a patient) and transillumination imaging (transmission of high-intensity visible light through a patient) have not yet been addressed by NCRP.

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